Meeting Notes
Clinical Advisory Panel

November 15, 2000 - Room 4203, State Capitol, Sacramento

Panel Members Present – Antonio Linares, M.D.; Peter J. Panzarino, M.D.; Herbert A. Berkoff, M.D.; David Bergman, M.D.; John Alksne, M.D.

Panel Members Absent – Edward Savage, Jr., M.D.

Introductions – Jim Tucker, Chief Deputy Director and Antonio Linares, M.D., Medical Advisor to the Director, opened the first meeting of the Clinical Advisory Panel. The Panel members introduced themselves and provided a brief professional background and their areas of interest in issues involving managed care in California.

Responsibilities of the Clinical Advisory Panel – Dr. Linares outlined the provisions of A.B. 78 describing the function and role of the Panel.

- Defining Medical Necessity – Dr. Alksne asked whether the Panel would define "medical necessity" for purposes of the Independent Medical Review (IMR) system. Dr. Linares acknowledged the various definitions of medical necessity. He noted the IMR statute describes a process that looks at individual medical needs and applies the most relevant medical and scientific information that reviewers must use as the basis for their analysis. Since the reviewer determination rests on finding whether or not the service is medically necessary, these elements can be viewed as providing a meaning of the term. Dr. Panzarino noted the Panel should have input in any standardization efforts in defining medical necessity and acknowledged that the information from the Stanford project on medical necessity was very helpful.

- Dr. Bergman noted that there is often a gray area between the scope of benefits and medical necessity. Dr. Linares noted that from a day-to-day operational standpoint, the HMO Help Center would resolve those questions. The Panel may be called upon for guiding principles in the interrelationships that occur between coverage and medical necessity.

- Dr. Alksne asked whether the patient can appeal only if the plan has agreed that the issue is based on medical necessity. Tom Gilevich, DMHC Counsel, noted that the statute requires the Department to make an independent evaluation and the plan's categorization is not determinative. The Department is designated as the final arbiter in such questions on whether a case is eligible for review.

- Dr. Panzarino requested clarification on whether a person can appeal to the Department even if the issue remains undecided at the plan after 30 days. Tom Gilevich noted the provisions allow the enrollee to come to the Department after 30 days, even if the plan has not rendered a decision. In urgent situations, expedited procedures would also allow an earlier appeal to the Department.

- Relationship with other Committees. The joint relationship between Panel and the Advisory Committee on Managed Health Care was noted by Dr. Alksne and Dr. Linares.

Background on California's IMR System – Tom Gilevich provided an overview of the history of California's external review system under the Friedman-Knowles Act. The experiences of other states with independent medical review systems, especially the recent report from New York, were also provided. He described the changes coming into effect on January 1, 2001:

- Cases will be eligible for IMR based upon determinations that requested care is not medically necessity, in addition to denials based on experimental and investigational exclusions from coverage.

- The Department will administer the IMR process. The previous system required patients to seek review through their plan that contracted with accredited review organizations. Under the new process, the review organizations will be selected under a state contract and paid by the Department.

- The Department will determine whether a case is eligible for IMR and be responsible for ensuring the reviews are timely and their findings implemented by the plan, when necessary. This includes specific obligations to investigate or seek penalties when plans fail to comply with requirements relating to patient grievances or to the IMR process.

- The Department's access and oversight of the IMR system and the availability of information of the types of cases leading to IMR should allow the Department to help the health plan industry assess the adequacy of plan policies and procedures on medical developments.

Panel members asked about the handling of cases arising from denied claims for reimbursement and requests for out-of-plan services. Tom Gilevich and Dr. Linares noted that applications will be reviewed before they are submitted for IMR. The HMO Help Center will determine whether other criteria, contractual or regulatory, may apply to the issues presented. Included in that review is to confirm that the dispute concerns a disputed health care service based on medically necessary and not a choice of provider based on assertions of quality. Dr. Bergman noted that there is a relationship between the volume of cases and quality in several speciality areas that should fall under the purview of the statute and the Department.

Jim Tucker noted that the Department would look to the Panel for insight in informing the public about the availability of IMR to reconcile health plan disputes.

Dr. Alksne and Dr. Linares noted the role of the Panel in providing clinical oversight and becoming the accrediting entity.

Jim Tucker asked the Panel members to consider how it can provide the Department direction on the obligations of plans to provide basic health care services and the issue of coverage decisions. For example, what are the appropriate levels of care that should be made available? In collaboration with academic institutions, DMHC hopes to better define the obligations relating to medical necessity and overall, the overall standards of care applicable to managed care.

Public Comment

- Beau Carter, Integrated Health Care Association. Mr. Carter noted that his association has long advocated creating a statutory external review system. He described the Association's efforts in Stanford's medical necessity project and the fair amount of consensus developed from that study. Mr. Carter encouraged the IMR include clear and rigorous decision-making with an established hierarchy of evidence. He also suggested that the Clinical Advisory Panel entertain discussion on the need to define medical necessity. He mentioned a RAND/Department of Labor study is underway to study internal plan grievance and appeals processes. Another key issue of concern the Panel may wish to consider is the topic of patient safety.

- Jonathan Freudman, M.D., Medical Director, Blue Shield of California. Dr. Freudman shared some background in the IMR experiences of Blue Shield under Friedman-Knowles and their voluntary external review program. He noted some requested procedures have resulted in what would seem to be a disproportionate number of reviews. He expects this will be an operational challenge in the Department's IMR system, as well as problems in obtaining access to medical records and cases involving determinations involving medications and formularies. Dr. Freudman offered to assist in further discussions with the Department on these and other IMR issues.

- Asha Chopra, M.D., InterValley Health Plan. Dr. Chopra noted the issues faced by the medical group in determining the issues raised in a patient's grievance. Defining the disputed service is key since that determines the entire course of resolving the complaint. The difference between patient expectations and medical necessity has been exacerbated by the internet and other information resources. The implementation of legal requirements, such as grievance standards and IMR, requires an understanding of medical group and plan interactions, including fiscal relationships.

- Thomas J. Brady, M.D., MHN, HealthNet. Dr. Brady noted continuing debate and confusion surrounding recent legislation on mental health parity, particularly in the area of children's mental health services. At MHN they have had external review for several years and intend to continue their system after January 1st. He supported earlier comments supporting further discussion on defining the term medical necessity.

- Earl Lui, Consumers Union. Mr. Lui noted that the previous systems used to resolve appeals for denied services have not worked. That is the reason why IMR, among other remedies, have been developed for patients. He noted the legislature considered many of the issues discussed, including defining medical necessity and whether a hierarchy of medical evidence should be considered. He believes the IMR statute is reasonably clear and that these issues should not be revisited.

- Beth Capell, Health Access California. Ms. Capell noted that the listed medical and scientific factors in the IMR statute are of equal importance and no hierarchy or order of importance can or should be applied. The specific medical and personal needs of the

individual patient are critical for a proper analysis in the review. The absence of a definition of medical necessity is the result of the legislative debate and process. In particular, she noted that there is no cost/ benefit analysis involved in what is medically necessary. Overall, legislative initiatives dealing with prescription benefits, diabetes supplies and other disease-specific mandates were necessary because health plans were not adjusting to medical and scientific changes. The Clinical Advisory Panel and the new IMR system offers a chance to facilitate provider education and agreement about standards of care when medical technology and practices shift.

Jill Silverman, Institute of Medical Quality

Ms. Silverman presented an outline of the activities and roles played by the Institute for Medical Quality in the statutory IMR system under the Friedman-Knowles Act. The Institute continues to study the impact that IMR has had in California, expanding upon its accreditation standards that were uniquely crafted for California's needs. Included in its efforts were critical monitoring activities of the reviews conducted by the two accredited companies performing reviews.

Bobbie Reagan, Chief, DMHC HMO Help Center

Ms. Reagan described the process developed by the HMO Help Center to receive and evaluate applications for IMR. The staffing of the Center by consumer service representatives, attorneys and nurses will ensure an efficient and accurate assessment of whether cases should be referred for IMR or handled as complaints under the existing systems within the Department.

She described the different criteria and timelines for expedited and standard reviews under the statute. She also notes that the Center is aware that for practical purposes, some reviews should be deemed "urgent" and will require prompt handling even though not meeting the specific criteria for expedited reviews.

Panel members asked about the involvement of treating physicians in determining whether a case should be expedited in the IMR process. Ms. Reagan described the presumptions accorded to the requesting physician in determining the review's priority. In response to a question from the Panel, Ms. Reagan noted the Help Center is purchasing a software system to manage, track and report the IMR process. It will be capable of generating automatic reports for the Panel's consideration.

Tom Gilevich noted the status of the contracting process and that a minimum of three reviewers will be required for experimental and investigational reviews. More than one reviewer may be required in medical necessity cases, depending upon the issues presented.

Dr. Alksne asked whether issues surrounding hospital stays would be eligible for IMR. Jim Tucker noted that time is critical in such circumstances and the HMO Help Center will seek to intervene while a determination is made on whether the matter is eligible for IMR or not. The statutory provisions relating to the filing and processing of urgent grievances to the plan and the Department were noted as existing remedies apart from the IMR process.

Dr. Bergman cautioned that some determinations of medical necessity may be at least as complex as issues relating to experimental and investigational services. Some cases may require

more than one reviewer or be an evidence-based review similar to the experimental/ investigational process.

Public Comment - Beth Salazar. Ms. Salazar noted that hospital stays was and has been a common issue in legislative debates. She would encourage the development of a system to respond to that consumer need.

Next Steps – Dr. Linares. Dr. Linares summarized the issues and areas discussed that should be considered for subsequent meetings:

- The Clinical Advisory Panel should schedule quarterly meetings.

- Discussion on whether a definition of medical necessity or guiding principles related to the process of medically necessity determinations should be developed and considered by the Department. The Panel and the review organizations should be in agreement on the guidelines to be used.

- Jim Tucker stated the members would be informed on the outcome of the IMR contracting process and a report will be available at the next meeting about the cases reviewed to date. In addition, the Department welcomes any suggestions that members had about the IMR system in general and how to provide oversight of the reviews.

- The Panel requested clarification of the guidelines used in the screening of emergency or urgent care claims regarding consistency and application of the prudent layperson standards.

- The Panel discussed developing a standard communication to provide information about the IMR program and the Department's clinical activities. Follow-up was requested to Dr. Bergman's suggestion that to reach some patients, putting links to the DMHC website on physicians' and other medical organizations' web pages and public service announcements should be considered by the Department.

[Corrections or comments regarding these notes should be provided to Tom Gilevich, DMHC Counsel at (916) 324-9024; FAX (916) 322-3968; TGilevich@dmhc.ca.gov.]